

PD4 Exh 1

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (collectively referred to herein as "Mallinckrodt") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Mallinckrodt and any facility owned or operated by the company registered, or who may become registered, with DEA to manufacture, distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. Mallinckrodt is registered with DEA at the facilities listed in Appendix A as manufacturers and distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A.

2. From January 1, 2008, through September 30, 2011, there was an epidemic increase in diversion of the controlled substance oxycodone, largely out of the state of Florida.

3. The United States alleges that Mallinckrodt, a manufacturer and distributor of oxycodone, knew about the diversion and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion.

4. As a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.

5. Furthermore, Mallinckrodt had an obligation to act only as authorized by its DEA registration including the responsibility to distribute its drugs legally through legitimate channels. The United States alleges that even though Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales. Furthermore, the United States alleges that Mallinckrodt never notified the DEA of the suspicious orders in violation of the CSA.

6. Over the past several years, Mallinckrodt alleges that it has implemented additional compliance safeguards to ensure that it meets its obligations as a DEA registrant and has taken significant steps to combat the diversion and abuse of opioids.

7. As of the date of this Agreement, DEA has not issued Orders to Show Cause against any of Mallinckrodt's DEA-registered entities.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of Mallinckrodt's entities, Mallinckrodt and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.
2. Covered Time Period. DEA contends that it has certain claims against Mallinckrodt under 21 U.S.C. § 823 and § 824 for engaging in the Covered Conduct as defined below from January 1, 2008, through the Effective Date of this Agreement (the "Covered Time Period").
3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

- a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
 - i. conduct adequate due diligence of its customers;
 - ii. detect and report to the DEA orders of unusual size and frequency;
 - iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- iv. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
- v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.

- b. With respect to the manufacture of controlled substances at Mallinckrodt’s Hobart, NY facility, Mallinckrodt’s alleged:
 - i. failure to take actual weights of controlled substances at all stages of the manufacturing process;
 - ii. use of a “target” tablet weight for purposes of reconciling batch records and determining the number of units of finished form manufactured even though the actual average weight of the tablets in any specific batch sometimes deviated from the target weight, resulting in discrepancies between the actual number of units of finished form manufactured and the extrapolated weight of the controlled substances in a batch and what Mallinckrodt’s records showed as the number of units of finished form manufactured and the extrapolated weight;
 - iii. commingling of dust collector waste and assignment of dust losses to particular batches without confirming how much dust was actually attributable to any specific batch;
 - iv. failure to check-weigh controlled substances received into the facility;
 - v. failure to maintain accurate records of substances transferred from the manufacturing process to Mallinckrodt’s analytical laboratories, maintaining such information only in individual technician logbooks that were not readily available for the DEA to review; and
 - vi. failure to include substances held in certain vaults/storage as part of the biennial inventory, and records provided for vaults containing discrepancies with respect to weight, missing substances, incorrect lot/batch numbers, and incorrect or incomplete drug names.

4. Acceptance of Responsibility. This Settlement Agreement is not an admission of liability for civil penalties for the Covered Conduct under the CSA. However, Mallinckrodt agrees that

at certain times during the Covered Time Period prior to January 1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007. Mallinckrodt further agrees that at certain times during the Covered Time Period, at Mallinckrodt's Hobart, New York facility, certain of Mallinckrodt's recordkeeping and physical security practices at that facility were, in some respects, not consistent with DEA regulation.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of three (3) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

I. Obligations of Mallinckrodt.

- a. Reporting of Suspicious Orders. Mallinckrodt acknowledges and agrees that the obligations undertaken in this Program do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances. Mallinckrodt recognizes the importance of the prevention of diversion of the controlled substances they manufacture. Mallinckrodt will design and operate a system that meets the requirements of 21 CFR 1301.74(b). Mallinckrodt's suspicious order system will be designed to utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.
 - i. In conjunction with informing DEA of suspicious orders, Mallinckrodt will include with each suspicious order report to DEA, the following information:
 - a. All DEA registrants identified in the order to include name, address, business type;
 - b. DEA registration #;
 - c. The order date;
 - d. Form number;
 - e. NDC number;
 - f. The dosage amounts of drugs ordered; and
 - g. A brief narrative providing a description of the details of the suspicious order report.
 - ii. On an annual basis during the term of the MOA, Mallinckrodt agrees to provide information to DEA at DEA's request regarding the process that it uses to monitor suspicious orders and to discuss that process with DEA upon request.

b. Chargeback Data Monitoring. As part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to “downstream” registrants. Mallinckrodt receives this type of data only after it is submitted to Mallinckrodt by the direct customer, which is after the controlled substance has already been distributed. Mallinckrodt will report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion. These reports will include the following information, to the extent known to Mallinckrodt:

- i. The identity of the downstream registrant and the direct customer(s) identified by Mallinckrodt engaged in the controlled substance transaction(s), to include each registrant’s name, address, business type, and DEA registration number;
- ii. The dates of reported distribution of controlled substances by direct customers to the downstream registrant during the relevant time period;
- iii. The dosage amounts reportedly distributed;
- iv. The transaction or order number of the reported distribution; and
- v. A brief narrative providing a description of the circumstances leading to Mallinckrodt’s conclusion that there is a risk of diversion.

c. Physical Security and Record Keeping.

- i. Mallinckrodt shall maintain a program to routinely and periodically train all employees at the Hobart facility to detect and prevent the diversion of controlled substances. Such training shall incorporate information on applicable laws and regulations, as well as Mallinckrodt’s internal compliance policies regarding both physical security of controlled substances and proper recordkeeping procedures. Such training shall be administered for each employee at or near the time of hire and at least every other year thereafter, with supplemental training administered concurrent with significant revisions to policy, or as needed.
- ii. Mallinckrodt shall maintain physical security measures in compliance with the CSA and its implementing regulations that shall include physical barriers with key-card access to all areas of the Hobart facility where controlled substances are stored and/or processed. Mallinckrodt shall also maintain a security camera system to record activities in such areas. The recordings from these cameras shall be maintained for at least ninety (90) days and shall be produced to DEA agents, task force officers, and/or diversion investigators upon request. Should Mallinckrodt undertake any construction, renovation, or reconfiguration at the Hobart facility, Mallinckrodt shall take appropriate action to implement the physical security measures described in this paragraph to that newly constructed,

renovated, or reconfigured location within a reasonable time after completion.

- iii. Mallinckrodt shall maintain policies and procedures to limit access to areas of the Hobart facility where controlled substances are stored and/or processed to only those employees, agents, and contractors who need access to those areas in order to perform their job functions or services.
- iv. Mallinckrodt shall maintain policies and procedures at its Hobart facility that provide for thorough background checks and drug testing as allowed under state and federal law at the time of hire; periodic, random drug testing throughout the period of employment as allowed under state and federal law; and disciplinary processes to address violations of Mallinckrodt's standard operating procedures or code of conduct.
- v. Mallinckrodt agrees that DEA may conduct an audit of the Hobart facility one (1) time per year during the period of the MOA and that the audit will cover a six (6) month period and that the audited products will be chosen at DEA's discretion.
- vi. For purposes of reconciling its batch records and calculating the number of tablets of finished form manufactured, Mallinckrodt will utilize the actual tablet weights of the first ten (10) and last ten (10) weights from each T1 chart produced during the manufacturing process to calculate a statistical average tablet weight. Mallinckrodt agrees that it will not use a "target" weight for purposes of reconciling its batch records or calculating the number of units manufactured to the extent such records or calculations are required to be made or kept under DEA regulations. Notwithstanding the foregoing, nothing in this agreement shall be construed to restrict Mallinckrodt's ability to make or keep records that meet its obligations under regulations promulgated by the Food & Drug Administration.
- vii. Mallinckrodt will include as part of its batch records at the Hobart facility the actual weight of the controlled substance throughout each stage of the manufacturing process. When product is moved in or out of storage, the weight of product will be verified through means such as by check-weigh procedures or by ensuring tamper evident seals are intact. During and after the packaging stage of production, batch records will also include the number of units of the controlled substance when moved in or out of storage areas, to include for destruction. Containers sealed with a numerical, tamper evident seal need not be re-weighed, provided the seal number and integrity is verified and documented.

- viii. In the manufacture of liquid formulations, Mallinckrodt will include in its batch records a yield reconciliation that includes the expected bottles, actual bottles and applicable waste.
- ix. Mallinckrodt will include as part of its batch records, on a batch-by-batch basis, the actual weight of the substances recovered from its dust collectors and vacuums used in the blending, tableting and packaging areas. This requirement to document actual weight on a batch-by-batch basis shall not extend to the substances recovered by the central dust or mixed cull filtration systems, but Mallinckrodt will document the weight of the substances collected by these systems. Records documenting the weight of the mixed culs shall include Mallinckrodt's estimate of the amount of each controlled substance in the mixed culs. Mallinckrodt shall document the calculation of its estimate of the total for each controlled substance in the mixed cull in a manner that reflects the estimated portion of the controlled substance culled from each batch from which the mixed culs are taken. Mallinckrodt shall make these records available to DEA upon request.
- x. Mallinckrodt will establish a process to document controlled substances transferred from the manufacturing process at the Hobart facility to each of its analytical laboratories. At a minimum, these documents will show the name of the substance, the form (e.g. tablet, powder, granulation, liquid or capsule) in which the substance is received at the lab, the date of each receipt, the actual weight of substances taken from the manufacturing process and the actual weight of the substances received at the laboratory, and the date and manner of distribution or destruction.
- xi. Mallinckrodt will include all controlled substances on hand in any vault, storage area, or laboratory as part of its biennial inventory at the Hobart facility. The inventory must document (1) the lot/batch numbers; (2) the name of the drug; (3) the number of sealed containers of tablets or capsules, the volume of liquid formulations and the weight of bulk powders and non-packaged dosage containers; (4) the drug strength (or drug concentration for liquid formulations); and (5) the unit size of the drug. The containers must be labeled. Notwithstanding the foregoing, nothing in this section prohibits Mallinckrodt from tracking laboratory reference standards, in-process testing materials, and other non-routine samples in existence at the time of the biennial inventory in a manner sufficient to allow such controlled substances to be tracked and verified in accordance with applicable regulations.
- xii. Mallinckrodt will record the actual weight for controlled substances it receives at the Hobart facility on the purchaser's copy of the DEA 222 Order Form. This weight will be determined by weighing the containers when received.

- xiii. Mallinckrodt will collect the waste from the Alpine Jet Sieve that is used for drug analysis at the Hobart facility after each analysis. The waste from each analysis must be stored in separate containers in the safe, with a label identifying its contents, until the containers are inventoried and collected for destruction.
- xiv. Mallinckrodt will document the Schedule III-V controlled substances transferred for destruction using the unit of measure used in the inventory management system for the product to be destroyed (e.g., substances from the blending state will be recorded in kilograms; substances in commercial bottles from the packaging phase will be recorded in bottles, etc.) The drug destruction documents should note the name of the drug, the form of the drug (e.g., powder, tablets, liquid, or culls), and the quantity in the appropriate unit of measures (e.g., weight, tablets, bottles).
- xv. Mallinckrodt shall maintain accurate logs of the receipt and disposition of controlled substances in the quality control labs at its Hobart facility.
- xvi. Mallinckrodt shall document the quantity of controlled substances lost in manufacturing and the causes therefor, if known. If Mallinckrodt determines that the variance between theoretical and actual yield indicates a loss in manufacturing that is greater than what is normal (normal variances are the result of many factors including, but not limited to, humidity and other environmental factors, slight scale variance, etc.), Mallinckrodt shall investigate such variances and attempt to determine the cause. Mallinckrodt shall create and maintain records of its investigation of any loss investigated under this subparagraph. The records shall reflect the cause of the loss, if known, and any action taken by Mallinckrodt to mitigate future losses in manufacturing. However, Mallinckrodt shall not be required to report such losses unless they otherwise meet the requirements for reporting significant losses found at 21 C.F.R. § 1301.74(c).

- d. Quota. Mallinckrodt agrees that its requests for active pharmaceutical ingredient ("API") procurement quota ("PQ") for oxycodone will not exceed in the 2017 calendar year the API PQ for oxycodone granted to Mallinckrodt in calendar year 2015, absent DEA's prior written approval, which shall not be unreasonably withheld. Mallinckrodt shall maintain all rights to challenge or appeal any quota determination by DEA as provided by applicable law and regulations.
- e. Cooperation. Mallinckrodt agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Mallinckrodt's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Mallinckrodt in regard to any pending or

threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, e.g., administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by Mallinckrodt or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

- f. Payment of Civil Penalty. Pursuant to the Settlement Agreement, Mallinckrodt agrees to a settlement payment to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) in the amount of \$35,000,000 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances and maintain effective controls to prevent the diversion of controlled substances. Mallinckrodt agrees to execute the Settlement Agreement simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment within five (5) days of the Effective Date of this Agreement.
- g. Any material breach by any Mallinckrodt facility of subsections II.1.(a)-(f) of this Agreement by Mallinckrodt after the Effective Date of this Agreement, where Mallinckrodt has not cured such breach as may be allowed under relevant law, regulation or this Agreement, may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of any of Mallinckrodt's DEA Certificates of Registration. However, nothing in this Agreement shall be deemed a waiver of Mallinckrodt's Due Process rights.

2. Obligations of DEA.

- a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that Mallinckrodt is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of Mallinckrodt under this Agreement, including the receipt of information and/or its participation in meetings with Mallinckrodt representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that Mallinckrodt is utilizing to meet its obligations under the CSA and the implementing regulations.
- b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.(a)-(b) of this Agreement.

- c. Upon a finding made by DEA during the term of this Agreement that Mallinckrodt failed to comply with its obligations, DEA, Diversion Division, shall promptly notify Mallinckrodt in writing of the specific obligations that DEA alleges that Mallinckrodt failed to follow. Within fifteen (15) calendar days after the receipt of the notification, Mallinckrodt shall respond in writing to DEA and either (a) state that it has cured or will cure within a specified amount of time the failure to comply with the obligations in question and describe the proposed cure in sufficient detail to permit DEA to evaluate the cure or proposed cure or (b) state that Mallinckrodt disputes that it has breached an obligation and the reasons for its belief. If Mallinckrodt believes that there is no deficiency or that it has cured an alleged deficiency noted by DEA, but DEA disagrees, DEA shall have the right to initiate an action for breach of this MOA in any federal court of competent jurisdiction. In addition, this provision is not intended to supplant or waive any other remedy available under the CSA and the implementing regulations and does not waive any civil penalties available to the United States under 21 U.S.C. § 842(c) for future misconduct.

3. Release by DEA. In consideration of the fulfillment of the obligations of Mallinckrodt under this Agreement, DEA agrees to:

- a. Fully and finally release Mallinckrodt, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and
- b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records Mallinckrodt submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At

Mallinckrodt's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Mallinckrodt is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by Mallinckrodt. Mallinckrodt fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Mallinckrodt has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Mallinckrodt) are the following:

- a. Any potential criminal liability;
- b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3(a) and (b);
- d. Any civil liability to the United States, other than the civil claims released in the Settlement Agreement; and
- e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Mallinckrodt, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained

in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Mallinckrodt represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Mallinckrodt further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Mallinckrodt immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA HQ: Drug Enforcement Administration, Diversion Division, 8701 Morrisette Drive, Springfield, Virginia 22152.

b. For Mallinckrodt:

Donald A. Lohman, Vice President - Legal
Mallinckrodt Pharmaceuticals
675 McDonnell Blvd.
Hazelwood, MO 63042

7. Disclosure. Mallinckrodt and the United States may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Mallinckrodt represent and warrant that they are authorized by Mallinckrodt to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any

federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act, as amended.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

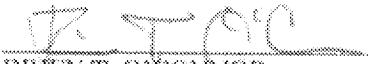
On Behalf of Mallinckrodt:


MICHAEL BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, LLC

Dated:


MICHAEL BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, plc

Dated:


BRIAN T. O'CONNOR
Ropes & Gray LLP
Counsel for Mallinckrodt

Dated: 7/17/17

On Behalf of the United States Department
of Justice, Drug Enforcement
Administration:


DEMETRA ASHLEY
Acting Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

Dated: 2/10/17

D. LINDEN BARBER
Quarles & Brady LLP
Counsel for Mallinckrodt

Dated:

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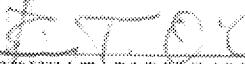
On Behalf of Mallinckrodt:

MICHAEL-BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, LLC

Dated:

MICHAEL-BRYANT HICKS
Senior Vice President and General Counsel
Mallinckrodt, plc

Dated: 7/7/17


BRENT T. O'CONNOR
Ropes & Gray LLP
Counsel for Mallinckrodt

Dated: 7/7/17


D. LINDEN BARBER
Quarles & Brady LLP
Counsel for Mallinckrodt

Dated: July 7, 2017

On Behalf of the United States Department
of Justice, Drug Enforcement
Administration:


DEMETRA ASHLEY
Acting Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

Dated: 7/10/17

APPENDIX A

LIST OF MALLINCKRODT DEA REGISTERED FACILITIES:

Mallinckrodt LLC
DEA Registration #RM0270037
172 Railroad Avenue
P.O. Box P.
Hobart, NY 13788

Mallinckrodt LLC
DEA Registration #RM0231821
172 Railroad Avenue
P.O. Box P.
Hobart, NY 13788

Mallinckrodt LLC
DEA Registration #RM0345163
3600 North Second Street
Saint Louis, MO 63147

Mallinckrodt LLC
DEA Registration #PM0037451
3600 North Second Street
Saint Louis, MO 63147

Mallinckrodt LLC
DEA Registration #RM0324602
385 Marshall Groves, MO 63119
Webster Groves, MO 63119